

Applicant: P. Stark et al.
Application No. 10/814,293

Docket No. 33976.00003

The Listing of Claims will replace all prior versions, and listings, of claims in the application.

LISTING OF CLAIMS

1. (Currently Amended) A multiparticulate bisoprolol formulation for once-daily oral administration, each particle comprising a core of bisoprolol or a pharmaceutically acceptable salt thereof surrounded by a polymeric coating, said coating comprising at least one enteric polymer coating material selected from the group consisting of cellulose acetate phthalate, cellulose acetate trimellitate, hydroxyl propyl methylcellulose phthalate, polyvinyl acetate phthalate, anionic polymers of methacrylic acid that dissolve at a pH from 5.5 to 7, Eudragit poly-acrylic acid, Eudragit-S, Eudragit-L, polyvinyl acetaldiethylamino acetate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate and shellac; said polymeric coating being effective to achieve an initial lag of bisoprolol release in vivo of at least 4-6 hours following administration and thereafter maintaining therapeutic concentrations of bisoprolol for the remainder of the twenty-four hour period.

2. (Original) A multiparticulate bisoprolol formulation according to claim 1, wherein the polymeric coating is effective to prevent quantifiable bisoprolol plasma concentrations in vivo for a period of at least 3-6 hours.

3. (Previously presented) A multiparticulate bisoprolol formulation according to claim 1, which contains a pharmaceutically acceptable salt of bisoprolol.

4. (Original) A multiparticulate bisoprolol formulation according to claim 3, wherein the salt is bisoprolol hemifumarate.

5. (Previously presented) A multiparticulate bisoprolol formulation according to claim 1, which has an in vitro dissolution profile which when measured in a U.S. Pharmacopoeia 2 Apparatus (Paddles) in phosphate buffer at pH 6.8 at 37°C. and 50 rpm substantially corresponds to the following: (a) from 0% to 10% of the total bisoprolol is released after 2 hours of measurement in said apparatus, (b) from 0% to 50% of the total bisoprolol is released after 4 hours of measurement in said apparatus; and (c) greater than 50% of the total bisoprolol is released after 10 hours of measurement in said apparatus.